

REMARKS

This paper is responsive to an *Official Action* that issued in this case on March 21, 2008.

In that *Action*, the Examiner rejected all pending claims as follows:

- Claims 1-6, 8 and 10 were rejected under 35 USC §112, ¶1;
- Claims 1, 4-6, 8, 10, 12-28 were rejected under 35 USC §103 as being obvious over U.S. Pat. No. 6,470,302 to Cunningham in view of U.S. Pat. No. 5,821,920 to Rosenberg.
- Claims 2-3 were rejected under 35 USC §103 as being obvious over Cunningham in view of Rosenberg and further in view of U.S. Pat. No. 4,850,960 to Grayzel.

Responsive to the *Action*, claims 1, 6, 12, and 19 have been amended and claims 2-3, 13-14, 18, and 20-28 have been canceled. Reconsideration is requested in view of the foregoing amendments and the following comments.

The Examiner alleged that claim 1 recited certain subject matter that was not described in the specification. Although applicant does not believe that this language was problematic under 35 USC §112, ¶1 for reasons that will become clearer below, it has been canceled from claim 1. It is believed, therefore, that this rejection should be withdrawn.

The Examiner rejected the claims based on prior art to Cunningham, Rosenberg, and Grayzel.

Amended claim 1 recites:

<p>An apparatus comprising: a needle/catheter module, wherein the needle/catheter module comprises: a needle; a catheter, wherein said catheter receives said needle, and wherein at least one of said needle or said catheter comprise a bevel; a sensor, wherein said sensor senses an orientation of the bevel; and pseudo skin, wherein said pseudo skin comprises an opening for receiving said needle and said catheter.</p>
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Cunningham makes no mention, whatsoever, of sensing the orientation of the bevel of a needle or catheter. The Examiner recognizes this, but notes that Cunningham discloses "knowing Rosenberg teaches of a pen-like stylus [that] allows for dexterous 3-dimensional manipulation."

And in the Background section of Rosenberg, the Examiner notes the mention of a probe by Immersion Medical. The Examiner notes that the Immersion probe "has six degrees of freedom which convey spatial coordinates (x,y,z) and orientation (roll, pitch, yaw) of the stylus to the host computer."

But the Examiner seemed to ignore that the fact that Rosenberg teaches *away* from using probes like the Immersion Probe for applications such as catheters, etc. Rosenberg states that "catheters work in a largely two dimensional environment" and, for such applications, "a less complex virtual reality device [than the Immersion probe] is desirable." See, e.g., col. 2, lines 42-67.

Regardless, there is no suggestion in these references for sensing the orientation of a bevel of a catheter or needle as used in a vascular access simulator.

Since certain limitations of claims 2 and 3 are now incorporated into claim 1, it is appropriate to discuss the Grayzel reference, which used in support of the rejection of claims 2 and 3.

Grayzel discloses a catheter with a bevelled tip to facilitate insertion of the catheter into pre-existing punctures. The Examiner argues that it would have been obvious to use a needle and a catheter with a bevel to simulate "a more realistic experience in performing the needle/catheter insertion."

As an initial matter, the presence of a bevel does not provide a more realistic experience in terms of force feedback from a simulation system. Neither applicant's claimed invention, nor any other simulator, provides a different "feel" or offers different resistance based on the orientation of the bevel as it penetrates psuedo skin.

The presence of the bevel enables the simulator to provide a more complete training experience to a user. That is, if a user does not appropriately orient the bevel, the user's performance will be graded lower by the simulator. Notwithstanding the importance of a bevel in an actual catheter or needle, there is nothing to suggest that the presence of a bevel in a vascular access simulator is an obvious feature. Since most simulators are focused on providing force feedback for actions taken, and since no simulator (including

applicant's) provides force feedback as a function of bevel position, sensing bevel position should not be considered to be an obvious feature.

With regard to applicant's amended claim language, it is noted that applicant's recitation of "a sensor, wherein said sensor senses an orientation the bevel" would reasonably convey to one skilled in the art exactly what is meant by such language, as explained at page 8 of applicant's previous amendment.

Those skilled in the art have known for many years that the rotational orientation of the tip of a needle or catheter's bevel, relative to the surface that it's penetrating, is important for patient comfort. It is noted that even though Grayzel is not directed to typical cutting bevels, but rather bevels that are intended to penetrate a pre-existing opening, the rotational orientation of the bevel is nevertheless important. As depicted in FIG. 2 of Grayzel, longitudinal stripe (2) is provided to identify bezel orientation. As noted at col. 6, lines 54-68 of Grayzel:

*In the fourth step ... introducing-dialating catheter **6** is over the guide wire **12** with the longitudinal stripe **2** uppermost, clearly visibel to the eye, and hence the leading point **4** of the bevel at the catheter's tip **1** is undermost... In this relationship, a minimum area of the catheter tip **1** engages the puncture hole Therefore, it provides for a minimum force of entry.*

Amended claim 12 recites an apparatus comprising:

<p>pseudo skin;</p> <p>a force-feedback assembly, wherein said force-feedback assembly is disposed beneath and is at least partially covered by said pseudo skin; and</p> <p>an end effector, wherein said end effector passes through said pseudo skin to reversibly couple to said force-feedback assembly, and further wherein said end effector comprises a needle catheter module, wherein said needle-catheter module includes:</p> <p>a needle;</p> <p>a catheter, wherein said catheter receives said needle, and</p> <p>wherein an end of at least one of said needle or said catheter comprises a bevel; and</p> <p>a sensor, wherein said sensor senses an orientation of said bevel.</p>
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Amended claim 12 is allowable over the cited art for the same reasons as claim 1. Namely, there is no disclosure or suggestion to provide a needle-catheter module having a needle and catheter, at least one of which includes a bevel, and a sensor for sensing the orientation of the bevel.

Conclusion

It is believed that claims 1, 4-6, 8, 10, 12, 15-17 and 19 now presented for examination are allowable over the art of record. A notice to that effect is solicited.

Respectfully
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